NECESSITY OF ROUTINE FOLLOW-UP VISITS AFTER DIAGNOSIS OF ACUTE OTITIS MEDIA: A COMPARISON OF PARENTAL REPORT OF SYMPTOMS AND PRESENCE OR ABSENCE OF ACTUAL PERSISTENT INFECTION

By

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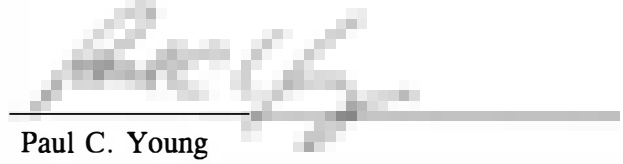

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To the Graduate Council of the University of Utah:

I have read the thesis of Julie L. Resheske-Fisher in its final form and have found that (1) its format, citations, and bibliographic style are consistent and acceptable; (2) its illustrative materials including figures, tables, and charts are in place; and (3) the final manuscript is satisfactory to the supervisory committee and is ready for submission to The Graduate School.

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ABSTRACT

Acute Otitis Media (AOM) represents one of the most commonly diagnosed conditions in pediatric primary care. Recent studies have questioned the practice of routine follow-up for all children diagnosed with AOM. The purpose of this study was to determine if the parental report of presence or absence of infection at the follow-up visit agreed with the exam performed by the health care provider. A convenience sample of parents of patients diagnosed with AOM at the Pediatric Clinic of Hill Air Force Base was used. Quantitative data were gathered and analyzed. The results showed that parents were accurate in their perception of persistent infection. The results of this study suggest that altering the current practice patterns by eliminating the routine follow-up visit for all patients diagnosed with AOM may be done without compromising patient health care outcomes.

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CHAPTER I

INTRODUCTION

Otitis media is one of the most commonly diagnosed conditions in pediatric primary care. It is estimated that at least 30% of the pediatric providers time is spent in diagnosing and managing acute otitis media (AOM), involving 25 to 30 million visits annually (Adderson, 1998; Bluestone, 1989; Fergie & Purcell, 1998; Hathaway, Katz, Dershewitz, & Marx, 1994; Klein, 1994). In addition to this condition occupying a large amount of the provider's time, the treatment provided to the patient most often involves antibiotic therapy. Approximately 30 million prescriptions are written annually for antibiotics in treatment of AOM, adding to the increasing problem of antibiotic resistance (Bluestone, 1989; Conrad, 1998; Paradise, 1995).

The current standard treatment regime for AOM is to treat the patient with a 5- to 10- day course of antibiotics and then ask the patient to return for an evaluation 2 to 3 weeks after the diagnosis to determine if the infection has cleared (Altemeier, 1998; Bluestone, 1989; Paradise, 1995). This pattern of routine follow-up has come under scrutiny lately due to the increased understanding of the normal course of resolution of an AOM. The effusion accompanying an AOM may persist for several months after the initial infection has cleared (Altemeier, 1998; Bluestone, 1989; Daly, 1991; Fergie & Purcell, 1998; Hathaway, et al., 1994). Routine examination of all patients 2 to 3 weeks after diagnosis may undoubtedly yield many who have either resolving AOM or a

persistent effusion as a consequence of a resolved AOM. Many providers will still choose to treat (with another course of antibiotics) those patients who show evidence of the above conditions, believing this represents persistent infection, and not understanding that complete resolution will take longer than 2 to 3 weeks.

Due to the increasing problems of antibiotic resistance, as well as the enormous costs associated with the treatment of AOM, it is imperative that pediatric primary care providers identify ways in which antibiotic use and costs could be reduced without any serious sequelae to the patient. Elimination of unnecessary visits and courses of antibiotics will decrease costs and limit the progression of antibiotic resistance.

Statement of the Problem

Proper diagnosis and treatment of AOM involves educating parents regarding the signs and symptoms of AOM, evaluation of the tympanic membrane and middle ear by a health care provider, and treatment of the infection with appropriate therapy. In addition to a visit for diagnosis and treatment, most practitioners believe that the child must have a visit after completing the treatment to assess whether or not the infection has cleared. The timing of this posttreatment evaluation visit varies by provider but is generally scheduled 2 to 3 weeks after completing the antibiotic (Hathaway et al., 1994; Schwartz et al., 1987). The findings at the follow-up exam dictate whether or not the child is placed on another course of antibiotic therapy. The problem occurs when the child has an infection that is clearing, but the follow-up visit shows evidence of effusion still present. Studies have shown that the effusion resulting from an AOM may take up to 3 months to clear completely. If an asymptomatic child is seen soon after antibiotic treatment has been completed, he or she may be unnecessarily treated for an unresolved or persistent

AOM when in reality the effusion is just clearing on its own natural course.

The magnitude of this problem is overwhelming. Considering approximately one third of all pediatric visits made to a health care provider are for otitis media and that all children diagnosed with AOM are instructed to return for follow-up, many available appointments will be taken up by unnecessary follow-up visits. The visit cost alone is a phenomenal expense, with increased expenses being caused by additional antibiotics (potentially unnecessary), lost wages, vacation and sick leave for parents taking the child to appointments, lost time from school for the child, unnecessary invasive procedures, as well as the larger, global issue of increased antibiotic resistance (from repeated courses of antibiotic therapy with stronger antibiotics).

The research surrounding the question of necessity of post treatment follow-up has been limited. Only two studies have looked at this issue. Schwartz (1987) concluded that the posttreatment evaluation could be delayed until 30 days after completion of treatment, thus avoiding misdiagnosis of a resolving AOM as a persistent or recurrent infection. Hathaway et al. (1994) looked at the correlation between parental report of signs and symptoms of infection with the objective evaluation by a health care provider. This study found correlation between parental report and actual presence or absence of infection to be extremely high, suggesting that parents know whether or not their child is better and could possibly be told to bring the child back in for follow-up only if he or she appears to have an unresolved AOM.

Purpose of the Thesis

Currently, only two research studies have specifically focused on the necessity of routine follow-up visits at 2 to 3 weeks postdiagnosis of an AOM. In addition, there have

been no studies of this type in a select population of military beneficiaries who bear no direct costs for their care when obtained in a military treatment facility. Therefore, the purpose of this study was to determine if the parental report of symptoms of AOM and assessment of presence of infection at the follow-up visit agreed with the actual presence or absence of persistent acute otitis media (PAOM) as determined by an objective exam from the health care provider. Specifically, if the parent is able to correctly identify signs and symptoms of PAOM, can the routine follow-up visit be eliminated for the majority of patients diagnosed with AOM?

Answers to the above questions will provide the primary care provider with the information necessary to implement a change in the current standard of care for patients diagnosed with AOM. The current literature supports the ability of the parent to identify the presence or absence of infection. Extensive research regarding the natural history of AOM also reveals that effusions may last up to 3 months and that 90% resolve spontaneously without additional antibiotic treatment.

The information gained from this study will be used as a foundation for future research into this subject in other settings as well as a basis for a change in the current standard of practice of AOM follow-up care. Based on the results of this study, one of the following options could be chosen: (1) The current practice of follow-up evaluations for all patients diagnosed with AOM will be validated as necessary and could be continued. (2) A policy change could be implemented, stating that when a child is diagnosed with AOM, the signs and symptoms of AOM will be reviewed with the caregiver, who will then be instructed to bring the child in for follow-up only if they feel the infection has not resolved.

CHAPTER II

REVIEW OF THE LITERATURE

Impact and Incidence of AOM

Otitis media is one of the most commonly diagnosed conditions in children, accounting for more than one third of all visits to the primary care provider (Adderson, 1998; Bluestone, 1989; Hathaway et al., 1994). The number of visits for this condition has doubled from 1975 to 1990, leading to a 200% increase in the diagnosis of AOM (Chartrand & Pong, 1998; McCraig & Hughes, 1995; Rosenfeld, 1996). McCraig (1995), Chartrand and Pong (1998) all agree that the increase in incidence can be directly attributed to the increasing use of day care facilities, with over 11 million children in day care in the United States.

Research studies have shown that the incidence of AOM is greater in children who are under age 3, attend day care centers (especially in the larger facilities), are exposed to tobacco smoke, have a family history of infection, are Caucasian, male, bottle fed and are put to bed with a bottle (Adderson, 1998; Chartrand & Pong, 1998; Daly, 1991; Hathaway et al., 1994; Kempthorne & Giebink, 1991). AOM is uncommon in infants under 6 months as well as in infants who are breastfed due to the protective effect of the maternal antibodies (Adderson, 1998; Daly, 1991; Kligman, 1992).

Treatment Variations

Historically, AOM was not treated with antibiotics and 80% of the cases resolved on their own (Kempthorne & Giebink, 1991). Despite this apparent success in resolution without treatment, 20% of patients developed complications, such as meningitis or mastoiditis (Kempthorne & Giebink, 1991). With the advent of antibiotic treatment for AOM, most of the complications were no longer seen (Bluestone, 1989).

The treatment of a patient with AOM depends on more than just the presence of an infection at a specific point in time. The provider must take into account the age of the patient, whether or not there has been a history of other infections, and what treatment has worked in the past. The provider then uses this information, along with his or her own experience and personal preferences to determine the appropriate treatment. There are several philosophies about proper treatment, with most variation originating from the country of the provider.

The most common first line antibiotic choice is amoxicillin (Bluestone, 1989; Kempthorne & Giebink, 1991; Klein, 1994; Kligman, 1992). It is effective against the four most common bacterial pathogens: *strep pneumonia, H. influenza, M. catarrhalis*, and *group A streptococcus*; is inexpensive and has relatively few side effects (Bluestone, 1989; Kempthorne & Giebink, 1991). Second line antibiotic recommendations are not as straightforward. The provider's personal experience and the resistance patterns of the local area provide the determining factors in making the appropriate choice, but an antibiotic effective against beta(b)-lactamase producing bacteria is usually necessary (Bluestone, 1989).

Treatment of AOM in the United States has traditionally been accomplished by

administration of a broad spectrum antibiotic immediately after diagnosis, and continued for 10- to 14- days (Conrad, 1998; Kempthorne & Giebink, 1991). Recently, American and European researchers have found that shorter duration of treatment may be equally effective as the typical 10- to 14- day courses (Dowell et al., 1998; Kempthorne & Giebink, 1991). Common practice in many countries outside of the United States is to treat the infection with comfort measures and to avoid the use of antibiotics altogether (Bollag & Bollag-Albrecht, 1991; Chartrand & Pong, 1998; Conrad, 1998; Dowell et al., 1998; Kligman, 1992). Several studies have examined the effectiveness of antibiotic versus placebo in treating AOM and have found only a small difference in the resolution rate and treatment failure (Chartrand & Pong, 1998; Paradise, 1995; Rosenfeld, 1995; Rosenfeld, 1996). Burke et al. suggest that the routine use of antibiotics is associated with incomplete resolution of AOM and may actually add to the sequele of middle ear effusion (1991). Other researchers have also asserted that due to the fact that antibiotics are only partially effective and many infections resolve on their own, antibiotic therapy may not always be necessary and should be reserved for the more severe cases (Canafax & Giebink, 1991; Rosenfeld, 1996). The consensus of most experts is that despite a bacterial etiology not always being identifiable, antibiotic treatment is necessary to avoid suppurative complications (Kligman, 1992; Rosenfeld, 1996).

Direct and Indirect Costs of Treatment

The direct costs of treating an AOM consist of the cost of the initial and follow-up office visits, prescription medications, consultation visits to other providers, treatment of complications and if necessary, surgical treatment. These costs have been estimated to be between three and four million dollars annually for the medical and surgical treatment

necessary (Adderson, 1998; Daly, 1991; Fergie & Purcell, 1998; Kligman, 1992; Schwartz, et al., 1987). With the trend towards using the more expensive antibiotics instead of the less expensive amoxicillin as first line therapy, there is a potential for the costs to increase even further.

The indirect costs associated with AOM are difficult to quantify. They include such costs as lost time from school for the child, lost work time for the parents, the increase in antibiotic resistance necessitating stronger, more expensive antibiotic therapy, and the emotional toll on the child and family resulting from clinic visits and invasive procedures. One analysis of these direct and indirect costs estimated them at $406 per episode and $2174 per episode for those cases involving surgical procedures (Fergie and Purcell, 1998).

Prevention of AOM has been suggested as one way to attempt to reduce these costs. Adderson states that altering environmental factors, utilizing immunizations, and selectively using antibiotic prophylaxis could result in a 25% reduction in AOM episodes with a cost savings of over one billion dollars annually (1998). Delaying initial antibiotic treatment and nontreatment of asymptomatic effusions after AOM are other methods suggested to reduce costs and assist in preventing the rising rate of antibiotic resistance (Conrad, 1998; Dowell et al., 1998).

The Increasing Problem of Antibiotic Resistance

Approximately 30 million prescriptions are written each year for the treatment of otitis media (Bluestone, 1989). With studies showing that up to 80% of the infections would resolve on their own without antibiotic treatment, one could easily argue that many of these prescriptions are written, and thus taken, unnecessarily. Chartrand and Pong

state that such over diagnosis and subsequent over use of antibiotics is the primary reason for the increase in antibiotic resistance we are seeing today (1998). In addition to the over diagnosis and over treatment of AOM, many patients do not take the medications as ordered or quit taking them early, thus offering a prime environment for the development of resistant bacteria.

B-lactamase production is one method bacteria have developed to increase their resistance to antibiotics. A significant increase in production of this enzyme has occurred in the last 10 years, with 40 to 50% of *H. influenza* strains and 80 to 100 % of *M. catarrhalis* all producing b-lactamase (Block, 1998; Klein, 1994; Kligman, 1992; Rosenfeld, 1996). Amoxicillin is still an effective first line medication despite the increase in b-lactamase production. However, when Amoxicillin is not effective, second and third line medications that are effective against b-lactamase producing organisms must be used. These medications are much more expensive and may be adding to the increasing prevalence of resistant bacteria.

Penicillin resistant *S. pneumoniae* is also on the rise, with up to 40% being resistant (Adderson, 1998). With penicillin resistant *S. pneumonia*, an entirely different mechanism of resistance is at work. In this situation, the presence of a b-lactamase producing enzyme in an antibiotic is not important, but necessitates the use of a stronger antibiotic that is effective against the alteration in penicillin-binding proteins. (Conrad, 1998; Paradise, 1995). This situation is much more concerning than b-lactamase resistance, as there are currently no oral antimicrobials effective against these types of organisms (Conrad, 1998).

The pattern of utilizing second or third line medications to treat an initial episode

of AOM may actually increase the incidence of treatment failure as well as add to the problem of increasing antibiotic resistance (Chartrand & Pong, 1998; Rosenfeld, 1996). Penicillin resistant *S. pneumoniae*, which can cause persistent AOM, is also increasing, especially among younger children who attend large group day care facilities and children who have recently been treated with a beta-lactam antibiotic (Rosenfeld, 1996). An overuse of all antibiotics, especially in the closed environment of day care centers, contributes to the increase in bacterial resistance (Chartrand & Pong, 1998, McCraig & Hughes, 1995; Paradise, 1995). Ultimately, the benefit to the patient must be examined with respect to the global public health risk of increasingly resistant bacteria.

Diagnostic Criteria/Use of Tools to Confirm Diagnosis

Complete visualization of the tympanic membrane (TM) is necessary to accurately determine the presence of infection. In addition to making an assessment of the color and position of the TM, the provider must also determine the mobility of the TM.

One of the problems surrounding making an accurate diagnosis of AOM is the subjective nature of the assessment (Bollag & Bollag-Albrecht, 1991). Providers use a visual examination of the TM, taking into account color, presence of fluid, and mobility of the TM along with the symptoms reported by the parents and patients. There is a high degree of provider variability in making the assessments and subsequent diagnosis, thus making the diagnosis of AOM questionable at times (Bollag & Bollag-Albrecht, 1991; Dowell et al., 1998).

A pneumatic otoscope is an essential tool for the accurate diagnosis of AOM. Color alone is not a sufficient measure of assessment as a reddened TM may be caused

by crying or fever and not by the presence of infection (Altemeier, 1998; Bluestone, 1989; Kempthorne & Giebink, 1991). When pnuematic otoscopy is used, position, color, degree of translucency, and mobility all must be assessed (Dowell et al., 1998; Klein, 1994). Pneumatic otoscopy requires the use of an otoscope with an airtight seal to observe for movement of the TM when air is insufflated into the canal. By observing the presence or absence of movement, the provider can make an assessment regarding the presence of fluid in the middle ear. This information will be used, along with other subjective and objective information, to make the diagnosis of AOM (Bluestone, 1989; Kempthorne & Giebink, 1991; Klein, 1994; Paradise, 1995). Pneumatic otoscopy adds a measure of objectivity to an otherwise very subjective and symptom dependent diagnosis.

Other tools available to assess for presence of fluid in the middle ear include tympanometer, acoustic reflectometer, and tympanocentesis. Both the tympanometer and the acoustic reflectometer offer more sophisticated assessment of the middle ear status, but standards have not been set for their interpretation (Kempthorne & Giebink, 1991). Tympanocentesis is the only method that determines the true status of the middle ear, but most pediatric providers are not skilled in the technique, and it is considered extremely invasive for all but the most severe or nonresponsive cases of AOM (Kempthorne & Giebink, 1991).

Normal Etiology of an AOM

Otitis media normally begins when bacterial or viral organisms present in the nasopharynx migrate to the middle ear, replicate, and cause edema and eustachian tube malfunction (Adderson, 1998). Often times, this is preceded or accompanied by other upper respiratory infections. Several researchers have theorized that AOM is part of a

myriad of middle ear pathology that can range from asymptomatic disease to acute infection to chronic effusion (Kempthorne & Giebink, 1991). Each part of the spectrum has different manifestations that need to be addressed and treated differently. As a single entity, AOM may be symptomatic or asymptomatic, may progress rapidly or may linger for days before causing pain and/or perforation, and resolve spontaneously or need treatment with antibiotics.

The organisms most commonly responsible for these infections are *Streptococcus Pneumoniae* (25 to 50%), *Haemophilus Influenza* (15 to 30%) and *Moraxella Catarrhalis* (3 to 20%) (Adderson, 1998). It is possible to have several organisms cultured from one middle ear, as well as different organisms from the right and the left ear. In addition, 20 to 30% of cultures show no pathogenic bacteria (Chartrand & Pong, 1998).

Spontaneous resolution of AOM is very common, most often occurring in children older than 2 years, when the TM has not perforated, and in children with no underlying anatomical abnormality, immune deficiency, or history of recurrent disease (Berman et al. 1987; Conrad, 1998). Several studies have compared the use of antibiotics versus placebo in treatment of AOM and found that between 86% and 92% of children treated with placebo had resolution of AOM (Chartrand & Pong, 1998; Rosenfeld, 1996). Rosenfeld also examined the use of other unconventional treatments of AOM and deduced that with the high occurrence of spontaneous resolution, these other therapies could also be interpreted as effective treatment without actually providing any real therapeutic benefit (1996).

AOM may resolve on its own or with the assistance of antibiotic therapy. After the acute infection has cleared, there is often an associated effusion that may take up to 3

months to completely clear (Berman, 1996; Fergie & Purcell, 1998; Kempthorne & Giebink, 1991; Klein, 1994; Rosenfeld, 1996). The presence of effusion is quite common, occurring in approximately 50% of all children diagnosed with AOM. Some providers choose to treat the resultant effusion with antibiotic therapy, but this issue is controversial and of questionable effectiveness (Dowell et al., 1998; Kempthorne & Giebink, 1991; Rosenfeld, 1996). The effusion is most often related to the inflammatory process associated with the acute infectious process, which is an expected course of AOM, for which antibiotics are of no benefit.

Untreated AOM, Treatment of PAOM, and Unresponsive AOM

One of the main arguments for antibiotic treatment of AOM is the reduction in risk of suppurative complications. Complications such as meningitis, mastoiditis, chronic effusions, and intracranial infections, which were common prior to the introduction of antibiotic therapy, have been decreased quite considerably (Bluestone, 1989; Conrad, 1998; Klein, 1994). In countries other than the United States where antibiotic therapy is not used as readily, there have been no studies that have shown that the incidence of suppurative complication is higher. In addition, these countries have also seen a reduction in the incidence of suppurative complications despite the infrequent use of antibiotic treatment (Conrad, 1998).

PAOM after the initial treatment may either be the result of the normal course of inflammation after AOM or a persistent infection due to the initial antibiotic not killing all the bacteria present. If the cause is determined to be continued infection a course of second line antibiotics is usually sufficient to clear the infection (Rosenfeld, 1996). If there are no signs or symptoms or infection, the inflammation is allowed to resolve on its

own without additional treatment.

Conductive hearing loss is usually not a problem with isolated cases of AOM but rather becomes an issue with otitis media with effusion (OME) that persists greater than 3 months. This may cause a significant impact on the child's speech, language development and developmental process if not identified and addressed early (Fergie & Purcell, 1998; Kligman, 1992). Speech and language development should be assessed in children who have frequent episodes of AOM as well as those who have effusions that persist longer than 3 months (Kligman, 1992).

AOM may fail to resolve despite the use of antibiotic therapy. One common cause of treatment failure is the inability of the antibiotic to effect an optimal middle ear concentration to kill the bacteria. Canafax and Giebink (1991) report a study that showed the middle ear concentration of antibiotic was only 41% of that necessary for amoxicillin, 23% for cefaclor, 27% for sulfamethoxazole, 20% for sulfisoxazole, and 10% for erythromycin. As discussed earlier, antibiotic resistance is another increasingly common reason for unresponsive AOM. The use of stronger, more potent antibiotics is ultimately necessary to treat these types of infections.

Posttreatment Follow-up Patterns

Providers generally have recommended that patients return for a follow-up examination after completion of treatment to determine if the infection has resolved. The timing of this visit has been set at anywhere from 2- to 6- weeks after treatment and based on a variety of criteria (Berman, 1996; Bluestone, 1989; Bollag & Bollag-Albrecht, 1991; Paradise, 1995). Despite the lack of research evidence supporting the necessity of this visit, providers have continued to recommend routine follow-up. Recently, however,

several researchers have defined problems associated with the timing of the follow-up visit and have recommended either delaying or omitting the follow-up visit altogether.

Despite studies indicating that effusion alone is not a sign of persistent infection, many providers mistake this middle ear fluid as a sign of an infectious process and choose to administer an additional course of antibiotics. This is usually unnecessary as the condition is not infectious but rather proceeding through the normal process of resolution and will most often resolve on its own in several months (Dowell et al., 1998; Schwartz et al., 1987).

Theoretical Framework

The theoretical framework to be used for the foundation and guidance of this study is Pender's Health Promotion Model. Application of this theory to the assessment of the accuracy of parental perception of resolution of infection will assist in understanding the knowledge the parents have regarding how symptoms are related to the health or illness status of the child. The theory highlighted certain variables that influence an individual's understanding of health status and incentive to change current health behaviors.

The underlying assumption of the Health Promotion Model is that the clients must take an active role in shaping and maintaining health behaviors and adjusting the environmental context of those behaviors when they are able (Pender, 1996). One specific assumption is that people have the capacity for self-awareness and are able to assess their own competencies. The theoretical model is made up of three sections: Individual Characteristics and Experiences, Behavior-Specific Cognition's and Affect, and Behavioral Outcome, each having several variables that contribute to the health

behavior of an individual (Pender, 1996). In Pender's theory, if an individual feels that certain behavior is important to his or her health status, he or she will act on that behavior to elicit a specific goal or outcome. In relation to this study, the parent is being given information to make an assessment of the health status of the child and therefore can impact how the child is subsequently treated.

Extensive research has been done using this theory as a basis for assessment of overall health promoting behaviors as well as specific behaviors such as exercise and hearing protection (Pender, 1996). Researchers have analyzed from 5- to 12- of the variables at a time and found that certain variables are more predictive than others of subsequent health promoting behaviors. Most of the investigators have looked at the behavior of a specific individual or group, but the model can be easily used in assessment of the health promoting behaviors the parent exhibits while caring for their dependent children. Specifically, the individual characteristics of the parent, encompassing their prior behavior and personal factors, will impact the behavior-specific cognition and affect they exhibit when faced with making decisions about the health care of their child. The parent must determine if there are any benefits or barriers to seeking care, the perceived self-efficacy of the behavior, and any active related affective responses that must take place prior to accomplishing a specific behavior.

This study examined the ability of parents to make informed assessments of the child's health status with the goal of encouraging the parents to seek care only if they felt it was necessary. By giving parents the education, knowledge, and reinforcement that they are able to accurately assess their child's condition, we are enabling them to take more responsibility for their child's health status. The key to the effectiveness of this

theory in the study is that providers have the ability to influence the behavior-specific cognitions and affect of the parent by providing education, information, and the reinforcement that the parent is an accurate judge of the health status of the child. This concept and theoretical framework will provide the basis for the design and method of this study.

Significance and Rational for the Study

The practice of routine follow-up visits (timing and necessity) has a limited research basis. The rationale for these visits shows considerable provider variation and has been shown to be of limited benefit when the patient is seen while the effusion is still resolving. Research by Hathaway et al. (1994) has shown that parents are able to identify when their child's AOM has resolved and recommended that follow-up be only selectively offered.

The practice of routine follow-up visits for all patients diagnosed and treated for AOM has resulted in increased costs to patients and third-party payors, increased invasive procedures, and may have contributed to the increase in antibiotic resistance. Additional, stronger courses of antibiotics are often administered for conditions that may resolve on their own. Since the literature cannot the support the necessity of this visit, it is a practice that must be evaluated and possibly changed. Investigators have already identified certain patients and conditions that predispose an individual to complications or persistent infections. We must now evaluate the necessity of the follow-up visit for those patients who do not exhibit signs or symptoms of persistent infection.

Research Questions of the Thesis

Several answers to questions may offer insight into how much parents understand about the etiology of AOM and the symptoms that signify an acute infection versus the presence of a persistent effusion. The parents/guardians of the children involved in the study have been given written information about the diagnosis and the signs and symptoms of AOM. They were then asked to use this information at the follow-up visit to make a judgment of whether or not the infection had resolved. The research questions are as follows:

1. What percentage of patients actually return for the recommended routine follow-up visit?
2. Does the parental report of presence or absence of infection agree with the presence or absence of PAOM as determined by the provider exam?
3. What symptoms from the parent's perspective are most commonly associated with the presence of AOM after treatment completion?

Operational Definitions

For the purposes of this research, specific concepts will be defined to assure consistency in evaluation and diagnosis of subjects. As stated in the review of literature above, the diagnosis of AOM has certain characteristics that must be met in order to accurately state that the patient has AOM.

AOM — Acute otitis media - A bulging tympanic membrane with evidence of fluid or air bubbles behind the membrane; opaque, red, or dull in color (identified with an otoscope); decreased movement of the tympanic membrane by pneumatic otoscopy exam; accompanied

by symptoms of fever, irritability, pain, vomiting, anorexia, diarrhea, purulent discharge, or hearing loss (Altemeier, 1998; Bluestone, 1989; Canafax & Giebink, 1991)

PAOM — Persistent acute otitis media - An AOM, as defined by the above signs and symptoms, that has continued despite treatment with a complete course of antibiotics. Usually indicating treatment with an alternative course of antibiotics is necessary to effect a cure (Rosenfeld, 1996).

OME/SOM — Otitis media with effusion/serous otitis media - A middle ear effusion that has persisted after a complete course of treatment with antibiotics. Effusion is determined by presence of clear or colored fluid visible behind the TM and decreased or absent mobility of the TM. This may be present for several months after treatment for AOM or may be unrelated to an episode of AOM (Bluestone, 1989).

UAOM — Unresponsive acute otitis media - An AOM, as indicated by the continued signs and symptoms of the initial presentation, that did not begin to resolve in 24 to 48 hours after the initial course of antibiotics was initiated, usually necessitating a change in the antibiotic (Berman, 1996).

CHAPTER III

METHODOLOGY

Design

A prospective design was used in this study, focusing on the association between parental impression of resolution of AOM in the child and the diagnostic impression of the provider. The child and his or her parent(s) were seen at initial diagnosis of AOM and again at the follow-up visit 14 to 21 days after diagnosis of AOM. Data were collected at the follow-up visit after the parent has agreed to participate in the study.

Setting

Hill Air Force Base Pediatric Clinic is a multiservice Pediatric Clinic offering services that include well baby and child care, physical examinations, acute illness care, routine visits for any nonacute type complaint, chronic disease management and evaluation for referral to subspecialty clinics. One board-certified pediatrician and two certified pediatric nurse practitioners as well as three medical technicians and one registered nurse staff the clinic. Most appointments are made through an appointment line staffed with clerks who schedule appointments for all clinics in the facility, with the exception of follow-up appointments which are scheduled by the Pediatric Clinic staff within the time frame requested by the provider.

The clinic outpatient records department maintains the patient records. Patient

charts are obtained from this department by the clinic staff or the patients prior to the scheduled appointment. Labs, radiographs, and prescriptions are all ordered by the provider via the computer with the data related to ordering and prescribing available in the computer database. Occasionally, previous records are unavailable at the scheduled visit due to being lost or a recent transfer to this base.

Sample

A convenience sample of patients presenting to the Pediatric Clinic of Hill Air Force Base (AFB) and diagnosed with AOM were asked to participate in the study. Sixty patients between the ages of 6 months and 12 years were included in the study. The length of the study was 3 months and was begun after approval from the IRB at the University of Utah and the Hill AFB Clinic. Exclusion criteria included: the presence of pressure equalization tubes (PET), AOM within 1 month of this episode, immunocompromised status, anatomic abnormalities of the ear canal or upper respiratory system, other associated illnesses requiring antibiotics, use of antibiotic prophylaxis, and the inability of the parent to read or comprehend English.

Instruments

The AOM Information and Instructions form (Appendix A) was given to the parent by the provider after the child was diagnosed with an AOM and the parent had agreed to participate in the study. The form contained information including the name of the antibiotic the child had been prescribed, signs and symptoms of an ear infection, and when to call the clinic if the symptoms were not resolving. The date and time of the scheduled follow-up appointment were added to this form after the appointment was

made by the office staff and confirmed with the parent.

The Patient Log form (Appendix B) was used as a means of keeping track of patients accepted into the study. The form consisted of four columns in which to record the patient name and identification number, the date of the diagnosis, the date scheduled for the follow-up visit and the provider who saw the patient.

The Study Information Sheet/Consent (Appendix C) provided information on the name and purpose of the study. It also provided information on the process that took place when the parent chose to participate in the study. In the form, parents were given the name of the researcher and phone numbers to obtain more information or have any questions answered. This form included a place for the parent and researcher signatures, which, when signed, served as the agreement to participate in the study. The researcher and the parent both kept a copy of this form.

The Follow-up Visit Questionnaire form (Appendix D) was completed by the parent when he or she presented for the follow-up visit. The questionnaire contained a list of 10 symptoms that the child could be experiencing at present. Marks were made next to the symptom or symptoms that the child was experiencing at that time. If the child had no symptoms, that space on the form was marked. After these symptoms were listed, the parent was asked seven questions regarding whether or not he or she felt the infection had cleared up, what antibiotic the child was on, whether the child took the medication as ordered, how long the child had symptoms after starting treatment, any history of recurrent ear infections, and if the child had been seen by any provider since the diagnosis of AOM.

The Follow-up Visit Provider Exam form (Appendix E) was completed by the

provider after the child was examined. Notation in this section included the color of the TM, mobility, presence of fluid or air bubbles, presence of PET, and if the TM was not visualized. The provider also noted if the exam was normal, or if there was evidence of continued infection or other disease. This form included an area for a pictorial description of the appearance of the TM. At the bottom of this part of the form was a statement asking if there was concurrence between the parental perception and the provider exam. The researcher completed this statement.

This form was pretested on 10 patients and parents to determine ease of use and effectiveness of data collection. No changes or clarifications were needed after this initial pretesting. Content utilized in construction was based on information obtained in the literature review pertaining to signs and symptoms of AOM, essential elements of the provider exam, and history and demographic information.

The Ear Recheck Form (Appendix F), which was used for all patients being seen for follow-up after an AOM, was also completed when the patient was examined by the provider. This form was placed in the chart as a permanent part of the patient's record.

The Follow-up Visit Questionnaire and Follow-up Visit Provider Exam forms (Appendix D and E) were the only forms to be utilized for data collection. The Patient Log form (Appendix B) was only for the convenience of the researcher and the clinic staff. Appendix A and C forms were used to give information on the diagnosis, signs and symptoms, medication, and follow-up visits and to obtain informed consent for participation in the study. These forms were essential to ensure consistent information was disseminated to all study participants. They also provided a means for parents to review the signs and symptoms of AOM, the normal course of infection resolution, and to

assist them in determining when an earlier return visit would be necessary.

Procedure

Approval for the study was obtained from the IRB of the University of Utah as well as the IRB at Hill AFB Clinic. Upon approval of the study, an inservice was provided to all Pediatric Clinic staff and providers which familiarized them with the study and the tools that were used to collect the data.

Providers were responsible for making the diagnosis of AOM and asking the parent of the patient if they would like to participate in the study. Diagnosis of AOM was made based on clinical objective assessment of the TM and middle ear with pneumatic otoscopy, along with the subjective report of signs and symptoms. The provider then chose the appropriate antibiotic and instructed the parents on medication use and when to return to the clinic for follow-up. The signs and symptoms of AOM were reviewed with the patient and parents at this time. Any parent of a patient diagnosed with AOM who met the study criteria was asked to participate in the study. The Acute Otitis Media Information and Instruction form (Appendix A) was reviewed and given to the parents prior to leaving the providers office.

Clinic staff made follow-up appointments for the patients in the time frame of 14- to 21- days from the date of diagnosis and noted the date and time on the AOM Information and Instruction Sheet (Appendix A). The log of patients in the study was kept at the front desk of the clinic (Appendix B). This log enabled me and clinic personnel to keep track of the patients in the study and to contact them if they failed to make the follow-up appointment. Two copies of the Study Information Sheet/Consent (Appendix C) detailing the objectives of the study were given to the parents after they

agreed to participate. One copy was signed by the parent and a witness, and kept by the researcher, and the other copy was given to the parent for reference.

At the follow-up visit, the parent was asked to complete the Follow-up Visit Questionnaire (Appendix D) about the child's current symptoms and their perception of whether or not the infection had resolved. The provider did not view the completed Follow-up Visit Questionnaire form (Appendix D) prior to performing the pneumatic otoscopy exam on the child. This ensured that the provider was not influenced by the parental report. After the exam, the provider used the Follow-up Visit Provider Exam form (Appendix E) to annotate the appearance and mobility of the TM as well as the results of the exam as normal, infection (BOM, ROM, LOM), or effusion (OME, SOM). Documentation of the visit was also recorded on the standard ear recheck form currently used in the Pediatric Clinic (Appendix F) and placed in the patient's chart.

After the parent and the provider had completed the above forms, they were given to the researcher who noted whether or not there was concurrence between the parental assessment of presence of infection and the objective exam by the provider. This was noted at the bottom of the Follow-up Visit Provider Exam form (Appendix E).

Data Analysis

Data from the questionnaire were quantitative. These data were analyzed using software from the Statistical Package for the Social Sciences (SPSS), including frequency distributions, Kappa, and Fisher's Exact Test. The alpha was set at .05 to determine significant relationships. Frequencies including central tendencies and variability were computed for the demographic data. Kappa was used to measure the agreement between the parental and providers report of presence or absence of infection. Fisher's Exact Test

was used to calculate the relationship between the symptoms reported by the parents and the parental perception of infection.

CHAPTER IV

RESULTS

The characteristics of the sample and the results of the data analysis are presented in this chapter. The analyses are introduced as they relate to the research questions of the thesis. For all inferential statistics, the alpha was set at .05. There were no missing data.

Sample

Eighty-two parents of patients diagnosed with AOM at the Hill AFB Pediatric Clinic were entered in to the study. Sixty of these individuals returned for the follow-up exam, completed the questionnaire and were examined by a provider. The information from these 60 patients was utilized in the evaluation of the data.

Characteristics of the Sample

The parents of the children who were diagnosed with AOM were the actual subjects of the study, but information about the children is integral to an analysis of the sample and will be detailed here. The age range of the sample spanned from 6 months to 12 years, with a mean of 2.9 years, a mode of 2.0 years and a median of 2.0 years. The majority (58%) of the children were 2 years old and younger. Other demographic data gathered in the questionnaire included the type of antibiotic the patient was prescribed (65% Amoxicillin), the compliance for that antibiotic (98% compliant), number of days

the patient had symptoms of AOM (90% less than 4 days), family history and personal history of AOM (see Table 1).

Research Question One

The first research question was to determine the percentage of patients that return for the scheduled follow-up visit. This question was easily answered by utilizing the patient log and counting the number of patients entered into the study by the providers and then counting the number of the patients who had completed questionnaires. The total number of subjects entered into the study was 82, of which 60 returned for the follow-up examination, resulting in a return rate of 73%.

Of the 22 patients who did not return for the follow-up visit, 20 were contacted to determine the reason they did not return for the visit. One was not contacted due to the family leaving the area and the other patient did not return messages that were left at the home. Eighteen of the 20 parents stated that the child was better and they felt it was unnecessary to return for the follow-up. Of the two other children who did not return, one had an appointment scheduled with a specialty provider, and one had been seen at a local emergency room for another reason and thought that the child did not need to be seen again.

Research Question Two

The second research question addressed the agreement between the parental report and the provider exam. On the questionnaire, the parent was asked if he or she felt the infection had cleared up. After examining the child, the provider also noted if the exam was normal, if there was presence of OME, SOM, or infection. The researcher then

Table 1

Demographic Data of Patients Diagnosed with AOM who returned for Follow-Up (n = 60)

	Frequency	Percent
Age		
0-1	20	33.3
2-3	21	35.0
4-5	15	25.1
6-12	4	6.6
Antibiotic		
Amoxicillin	39	65.0
Augmentin	6	10.0
Zithromax	10	16.7
Rocephin	2	3.3
Other	3	5.0
Compliance		
Yes	59	98.3
No	1	1.7
Days of Symptoms		
0-1	13	21.7
2-3	38	63.3
4-5	4	6.7
6-7	2	3.3
>7	3	5.0
History of AOM		
Yes	29	43.3
No	31	51.7
Family History of AOM		
Yes	34	56.7
No	26	43.3

analyzed the responses and noted if there was concurrence between the two evaluations.

In 54 cases there was agreement between the parental report of no infection and provider exam identifying absence of infection; six cases did not show agreement, resulting in an agreement value of 90%. The agreement between these two evaluations was analyzed by kappa, which measured the agreement between the evaluations of two raters when those two raters are evaluating the same item (the child). Using the kappa coefficient, which corrects for chance agreement between observers, the results identified a significant kappa value of -.209 ($p < .0001$) indicating that there is good interobserver agreement on presence or absence of PAOM (see Table 2).

Two children were thought by the parents to have no infection present but were found to have an infection present upon examination by the provider. Further evaluation of the demographic data of these two children showed that they were both males, 15 and 16 months old, with a personal or family history of AOM. They had both been given amoxicillin and had symptom resolution in 2 to 3 days after the antibiotic was started, but presented to the follow-up appointment with only the symptoms of cough/runny nose reported.

Research Question Three

"What symptoms were most commonly associated with the presence of AOM from the parents perspective after the completion of treatment?" was the third research question to be answered. Fisher's exact test was used to assess the significance of the relationship between the symptoms reported by the parent when the parent also reported that they felt the infection was still present. Of the 11 choices the parent had when stating what, if any, symptoms were present in the child, 7 were used in the analysis of

Table 2

Results of Agreement between Parental Report of Infection and Provider Determination of Presence or Absence of Infection (n = 60)

		Provider Exam Presence of Infection		
		No	**Yes**	**Total**
Parental Assessment Presence of Infection	**No**	48	2	50
	% of total	80.00%	3.30%	83.30%
	Yes	4	6	10
	% of total	6.70%	10.00%	16.70%
	Total	52	8	60
	%of total	86.70%	13.30%	100.00%

K = -.209

significance. Four were not used for analysis since they were not used by the parents: vomitting, ear drainage, other symptoms, and other choice being "no symptoms." Of the seven symptoms reported, the only two responses that showed significant association with the actual presence of infection as perceived by the parent and validated by the provider exam were pulling at ears (p = .004) and complaint of earache (p = .013) (see Table 3).

Similar analysis was done for the relationship between the symptoms reported by the parent and the results of the provider exam. The providers were not specifically examining the child's symptoms, only the objective assessment of the TM with pneumatic otoscopy, but the relationship between the reported symptoms and the

Table 3

Fisher's Exact Results of Comparison of Parental Reported Symptoms and Parental Reported Presence of Infection (n = 60)

		Infection		No Infection		p
Symptom		n	%	n	%	
1. Fever						0.083
	Yes	3	30%	4	8%	
	No	7	70%	46	92%	
2. Fussy/Sleep Problems						0.347
	Yes	3	30%	7	14%	
	No	7	70%	43	86%	
3. Poor feeding						1
	Yes	1	10%	5	10%	
	No	9	90%	45	90%	
4.Diarrhea						1
	Yes	0	0%	1	2%	
	No	10	100%	49	98%	
5. Cough						0.294
	Yes	6	60%	19	38%	
	No	4	40%	31	62%	
6. Pulling at Ears						0.004
	Yes	5	50%	4	8%	
	No	5	50%	46	92%	
7. Earache						0.013
	Yes	3	30%	1	2%	
	No	7	70%	49	98%	

presence of infection is important to understand. Of the eight symptoms reported, the two responses that showed significant association with the actual presence of infection were fever ($p = .043$) and cough ($p = .007$) (see Table 4).

At least one type of symptom was reported for 37 of the 60 subjects, but only 10 of the parents felt that the symptom(s) were indicative of persistent infection. Of the two subjects where the parent reported no infection and the provider found infection still present, the reported symptoms in both subjects were cough/runny nose.

Table 4

Fisher's Exact Results of Comparison of Parental Reported Symptoms and Provider Reported Presence of Infection (n = 60)

	Infection		No Infection		p
Symptom	n	%	n	%	
1. Fever					0.043
Yes	3	37%	4	8%	
No	5	63%	48	92%	
2. Fussy/Sleep Problems					0.12
Yes	3	38%	7	13%	
No	5	62%	45	87%	
3. Poor feeding					0.593
Yes	1	13%	5	10%	
No	7	82%	47	90%	
4.Diarrhea					0.867
Yes	0	0%	1	2%	
No	8	100%	51	98%	
5. Cough					0.007
Yes	7	88%	18	35%	
No	1	12%	34	65%	
6. Pulling at Ears					0.09
Yes	3	37%	6	11%	
No	5	63%	46	89%	
7. Earache					0.555
Yes	0	0%	4	8%	
No	8	100%	48	92%	
8. Other Symptoms					
Yes	0	0%	3	6%	0.646
No	8	100%	49	94%	

CHAPTER V

DISCUSSION

In this chapter, a discussion of the results that were presented in Chapter IV is provided. The research design is examined and discussed. A brief discussion of the usual pattern of care for patients diagnosed with AOM at the Pediatric Clinic of Hill AFB is provided, along with plans for a change in that protocol based on the results of this study. The results are examined, with particular attention to the compliance with the recommended follow-up, the report of symptoms present, and the agreement between parental perception and provider examination. Possible explanations for the findings are explored next. Finally, a discussion of implications for nursing, clinical practice, education, and the recommendations for future research are addressed. Limitations of the study are also addressed in this review.

Design

This research study used a nonexperimental, prospective, descriptive design. Only subjects that were diagnosed with AOM and met the study criteria were asked to participate in the study, therefore there was no manipulation of the independent variable, control group or randomization of the subjects necessary. The goal of the study was to ascertain whether or not the parents were able to accurately assess their child for the presence of a PAOM at the time of the follow-up visit. This assessment by the parent

was compared to the objective examination of the TM as done by the provider, blind to the parental assessment, which was considered the "gold standard." A prospective, descriptive design was appropriate for this purpose. Despite the fact that the study was accomplished in a military facility where cost of visits and medications were not a factor for the parents, the results can be generalized to any population in which a managed care organization or other payor has a desire to eliminate unnecessary visits and reduce costs.

One limitation to the study and the results is the instrument used for the data collection. This tool was developed by the researcher for the purpose of this study; therefore, the reliability and validity has not been established. The straightforward objective nature of the data argue for face validity. Parents did have the opportunity to ask the clinic staff for clarification of questions while completing the questionnaire, but there is the potential that parents could have misunderstood the instructions and thus completed the form incorrectly. During pretesting, attention was paid to the ease of use and readability, and there were no problems found. There were no missing data in the study, which strengthens the results and conclusions.

The sample was homogeneous as members of the military and dependents. All children had been diagnosed with AOM in this facility and in most instances, were scheduled follow-up visits with the same provider that had diagnosed the initial infection. The small number of clinic personnel assisted in maintaining a consistency of information given to the parent and an assurance that identical criteria was used for the diagnosis of AOM at initial and follow-up visits. This level of control is ideal and cannot be assumed that would be similar in other facilities of different sizes or with a more diverse population.

Usual Care Pattern

In order to put the results and discussion of them into perspective, an understanding of the usual pattern of care and follow-up in this Pediatric Clinic must be had, as well as the magnitude of this patient population. When a child is diagnosed with an AOM, the parent is given instructions on use of the medication, signs and symptoms to watch for that would signify the infection was not resolving, and is told to have the child seen again in 2 to 3 weeks to see if the infection has cleared up. The parent must then call the appointment line and make a follow-up appointment for the child.

Statistics are not kept on the number of patients diagnosed with AOM who subsequently return for follow-up exam so the number can only be inferred by the number of children diagnosed with AOM and the number of brief appointments (for ear recheck only) available. Approximately 4000 children are diagnosed with AOM each year in this Pediatric Clinic. There are only approximately 1500 brief appointments available each year, of which many often go unfilled. Some parents may also use an acute or routine appointment to have an ear recheck performed but this is generally not allowed as acute appointments are reserved for acute, new onset problems and routines are for problems lasting greater than 3 days. It can be inferred from this data that less than half of the children diagnosed with AOM are returning for the recommended follow-up exam. In this study, 73% returned for the follow-up visit, which was a much greater percentage than the general patient population. Despite this lack of follow-up in the general clinic population, there have been no incidences of suppurative complications or increased incidence of persistent OME with associated speech delays identified in this clinic population. For those children who do have frequent, recurrent AOM (> 6/year) or

have persistent OME for > 3 months, referral to an in-house Ear, Nose, Throat (ENT) specialist is provided.

Possible Explanations

As stated in this thesis under "theoretical framework," it was shown that people have the capacity for self-awareness and are able to judge their own competency in making health related decisions. In addition, it was shown that individuals will act on a belief if they feel it is important to the status of their health. This was evident in this study as the number of parents who brought the child in for the follow-up exam. Of the 22 parents who did not return, 18 made the decision to not return based on their own assumptions of the health status of their child. Of the 60 who did return for the follow-up visit, 54 were correct in their determination of the infection status of the child. Combined, this results in a 90% accuracy by the parents in determining presence or absence of infection. These results reinforce the understanding that education provided to the parents, as well as validation of their ability to make an accurate assessment of the health status of their child will increase their ability to continue this behavior in the future.

As stated earlier, 73% of the study participants returned for the follow-up exam. Several explanations are possible for this being significantly greater than the general population of the pediatric clinic. The parents knew they were part of a study and wanted to participate fully, thus returning for the visit even knowing that their child was feeling better. Also, having the parent make the follow-up appointment at the clinic before leaving, writing down the date and time of the appointment, and giving them written information about the study took away the possibility that they would not follow through

on making the appointment by phone through the appointment line. Due to the nature of the location and population of this study, these results cannot be interpreted as indicative of what other studies of similar type may experience.

This study confirmed the results of the study by Hathaway et al. (1994) which found that parents were accurate 97.1% of the time in determining that there was no infection present. Most parents are intimately aware of changes in their child's affect, activity level, and mannerisms. Health professionals are more inclined to desire some sort of objective assessment to determine what is going on with the patient. This study validated the fact that parents, without a means to objectively assess the middle ear of the child, were quite accurate in making a determination by subjective means. Looking at the results of these two studies, one is led to reconsider the necessity of the follow-up visit for most cases of AOM.

Research question number three was about whether symptoms noted by the parents were indicative of a PAOM as noted by the provider. Symptoms were noted by 37 of the 60 parents (62%), while only 10 (17%) of those parents felt that the symptoms were indicative of infection. Of those 10 parents who felt the child had PAOM, 6 were in agreement with the provider. The most commonly identified symptoms for these six children were cough/runny nose (4) and pulling at ears (4). As identified in the results section, the two symptoms that were significantly associated with PAOM from the parental perception were pulling at ears and a complaint of earache. One parent reported no symptoms but felt the infection was still present, which was confirmed in the exam by the provider. Interestingly, pulling at ears was significantly associated with PAOM from both the parental report and the provider exam. In the literature review, pulling at ears

was dismissed as not a good indicator of AOM and was more often associated with the presence of teething pain in the infant and child. This result may be unique to this study population or may be reflective of the ages of the children with the majority (58%) being 2 years old and younger. This age group generally has limited verbal skills, which may lead the parents to rely on more obvious symptoms such as pulling at the ears, cough, runny nose and increased irritability rather than the child telling the parent that they have ear pain or they cannot hear as well.

Several of the Follow-up Visit Questionnaires had comments such as "just started today" written next to the symptoms which were not used in the data analysis but gave insight into the number of reported symptoms. The questionnaire asked what symptoms the child was experiencing at present as well as how many days the child had symptoms after starting the antibiotics. The majority (90%) of the days reported for continuing symptoms was four or less. These data show that the symptoms of the initial infection had resolved with the initial treatment, but now new symptoms had arisen. These new symptoms may be a new infection starting or may have been unrelated to the presence of an infection.

The provider has the opportunity, at the time of diagnosis of AOM, to determine what symptoms the parent identified in the child, what caused the parent to determine that the child needed to be examined, and also the parent's level of comfort in evaluating the needs of their child. The provider also has the opportunity to provide further education to the parent who may not know what signs or symptoms may indicate a new or persistent infection. In this study, many of the signs and symptoms of AOM were listed on the information sheet that was given to the parent after the child was diagnosed

with AOM. This may have influenced the parent's ability to look for and identify those symptoms in the child.

Implications for Nursing

The explanation in the previous section creates important implications for nursing, especially in terms of the role of the Pediatric Nurse Practitioner.

Clinical Practice

The results suggest that parents are already making the decision themselves about whether or not to bring the child in for follow-up. Therefore, it is essential that the provider give accurate information about the signs and symptoms of AOM to the parent at the time of diagnosis. The parent must then be instructed to return to the clinic for reevaluation of the child if they identify any of the signs or symptoms. The signs and symptoms reported by the parents can be quite varied and may have no relationship to the presence of infection in that particular child. The provider must then educate the parent on identification of what symptoms the child was exhibiting prior to the diagnosis of AOM, and to watch for the persistence or reoccurrence of those symptoms.

The process of instructing every patient diagnosed with AOM to return for follow-up is also not necessary. A majority of these patients are not returning and the parents are able to accurately identify whether the infection has cleared or is persisting. This visit needs to be selectively offered to those children whose parents feel the infection has not resolved, cannot accurately identify the symptoms, or if they have a history of AOM or persistent OME (Hathaway et al., 1994). By eliminating or revising this process, we are making more appointments available for other acute or routine needs.

The time spent by the provider in educating the parent will be well spent when the only children brought in for the follow-up visit are those that truly need to be seen.

Education

The education of nurses and other medical personnel often focuses on understanding the physiology of disease and subsequent treatment. The results of this study validate the need for assessing the symptoms of the presenting illness, listening to the subjective assessment of the parent and patient, and thoroughly educating the parent on the signs, symptoms, and disease process.

As Pender (1996) noted in her Health Promotion Model, people will act on the information they have to make decisions about specific health behaviors. The education that nurses and other health care providers receive must include techniques in the assessment of caregiver knowledge and their ability to apply that knowledge for the benefit of the child. Much time is currently spent educating health care personnel in the assessment and treatment of specific disease, additional time must be spent in ensuring that providers understand the importance and necessity of teaching and listening to the patient.

Future Research

Future studies should look at the patterns of care, complications, and consequences once the follow-up visit recommendation is eliminated. First, after implementation of the protocol that all patients will not be asked to return for follow-up, a study should be done to determine the percentage of parents who still choose to bring the child back in for a recheck. By evaluating this, as well as the parent's reason for

bringing the child in, we will be better able to tailor our education to the needs of the patient population. Second, after routine follow-up visits have been eliminated, a study should be done to assess for any increase in the incidence of suppurative complications or OME that goes undetected after an episode of AOM. Persistent OME in the preverbal population is a significant concern and any increase in this incidence would need to be acted upon.

This research study was conducted in a very select group of individuals. The follow-up rate, compliance with medication, and the availability of free medical care, consultations, and medications may have influenced the significance of the outcome. To generalize outside of this group on the basis of this research alone would not be recommended. Using the results of the research that has already been done, along with the results of this research, however, would increase the credibility and validity of making changes in the current practice of AOM follow-up.

Summary Statement

Despite the limitations of this study, important information was gathered. The percentage of patients returning for the follow-up visit was larger than expected, as compared to previous studies and in the general population of the pediatric clinic. The agreement between the parental perception of infection and the presence of infection as determined by the objective exam of the provider was found to be significant, which was the result that had been anticipated. The parental report of symptoms was perhaps the most confusing of the data, as the symptoms that were significantly associated with parental report of infection, and validated by the provider exam, were those that were not deemed significant predictors in previous studies.

Implications for nursing from this study include the suggestion that the routine follow-up visit for AOM is eliminated and selectively offered to those children who are at highest risk for persistence and/or complications. In addition, increasing the amount of education provided to the parents, along with validation of the accuracy of their perception of the child's health status, will increase the ability of the parents to become even better advocates for their child's health. Future research of similar type in other settings and research on compliance and complications once the follow-up visit is eliminated is also necessary.

Addressing the problem of how best to serve our patients without over or undertreating, and still maintaining access to the pediatric clinic, is an ongoing challenge. Evaluating practices that have been adopted as standard of care, but perhaps are no longer appropriate is one way to address this issue. As costs of health care continue to rise and individuals are asked to take greater control of their own health care needs, our jobs as health care providers will be challenged and must be adapted. It is imperative that we offer education and information to patients and families to better equip them to meet these increased demands.

APPENDIX A

ACUTE OTITIS MEDIA INFORMATION AND INSTRUCTIONS

Acute Otitis Media Information and Instructions

1. Your child has been diagnosed with an ear infection (acute otitis media) and prescribed an antibiotic to treat the infection. The antibiotic is _____, please take all the medication as prescribed and instructed by your provider.
2. Signs and symptoms of an ear infection are: fever, fussiness, irritability, poor feeding, vomiting, diarrhea, tugging at ear, decreased appetite, complaint of ear pain, drainage from the ear, or hearing loss.
3. Your child may still have signs or symptoms for 24 to 48 hours after starting the medication. If symptoms last longer than this time, make an appointment for the child to be seen in the clinic.
4. A follow-up appointment is scheduled for _____. Your child's ears will be evaluated at that time to determine if the infection has cleared up.

APPENDIX B

PATIENT LOG

Patient Log

Patient Name/ID#	Date of Dx	Date of F/U	Provider

APPENDIX C

STUDY INFORMATION SHEET/CONSENT

Study Information Sheet/Consent

Necessity of Routine Follow-up Visits after Diagnosis of Acute Otitis Media: A Comparison of Parental Report of Symptoms and Presence or Absence of Actual Persistent Infection

Julie Resheske-Fisher, RN, Principal Investigator 801-771-1907 (24 hr number)

Background: You are invited to participate in a study designed to examine how well parents can assess their child's symptoms and determine if the ear infection has cleared up. The purpose of this study is to determine if the parental report of the presence or absence of symptoms of an ear infection at the follow-up visit is an accurate indicator of the actual presence or absence of an infection as determined by an objective exam from the health care provider.

Study Procedures: If you decide to participate in the study, please sign this consent form and return it to your health care provider. Your child will be scheduled a follow-up visit in 14 to 21 days to re-examine his/her ears. At the follow-up visit, you will be asked to complete a short questionnaire asking what, if any, signs and symptoms of an ear infection your child has. You will also be asked if you feel the infection has or has not cleared up.

Risks: No significant risks are anticipated as a result of your participation in this study.

Benefits: The information provided as a result of this study will help us to understand what signs and symptoms are most predictive of a persistent ear infection as well as how accurate parents are in assessing whether or not the child's ear infection has cleared up. There is no compensation for participating in this study.

Alternative Procedures: You may choose not to participate in this study. If you choose not to participate, this will not affect your relationship with your child's health care provider, the clinic, or the medical care your child receives.

Confidentiality: All information provided to the researcher will be kept strictly confidential. All questionnaires and forms will be kept locked and will be destroyed upon completion of the study.

Questions and Contact Person: I will answer any questions you may have concerning the study. You may contact me at 801-771-1907 (24 hr telephone number) or at 801-777-6214 during the normal duty day. If I am not there, please leave a message and I will contact you as soon as possible.

Institutional Review Board: If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board Office at 801-581-3655.

Medical Treatment or Compensation for Injury: In the event you sustain injury resulting from your participation in the research project, the University of Utah can provide to you, without charge, emergency and temporary medical treatment not otherwise covered by your own insurance. If you believe that you have sustained an injury as a result of your participation in this research program, please contact the Office of the Vice President for Research, telephone number 801-581-7236. By signing this document you are not giving up your right to pursue legal action against any and all parties involved with this research, in accordance with the Utah Governmental Immunity Act, Section 63-30-1:63-30-34 Utah Code Ann. 1953 (as amended).

Voluntary Participation: Your participation in this study is completely voluntary. If you do not wish to participate, the care your child receives will not change. You may chose to stop participating in the study at any time.

Unforseeable Risks: Although there are no significant risks anticipated as a result of your participation in this study, unforseeable risks may occur.

Right of Investigator to Withdraw Subject: If during the course of the study you no longer meet the inclusion criteria, the investigator may decide to stop your participation in the study without asking you.

Costs to Subjects: There will be no cost to you or your insurance company for your participation in this study.

New Information: Any significant new findings discovered during this research study that may influence your willingness to participate in this study, will be made known to you.

Number of Subjects: Approximately 100 families will be invited to participate in this research study.

Consent

I have read the above information and my questions have been answered. I desire to participate in this study and accept the benefits and risks. I understand that a copy of this consent document will be given to me.

_____ _____

Signature of Research Participant Date

_____ _____

Witness Date

APPENDIX D

FOLLOW-UP VISIT QUESTIONNAIRE

Date:_____Patient Name: _____ Last 4 of SSN: _____Age:____

Provider: _____

Parents fill out this section:

Please place a check by each symptom that your child is experiencing at present:

1. Fever_____
2. Fussy/Sleep problems_____
3. Poor feeding_____
4. Vomiting_____
5. Diarrhea_____
6. Cough, runny nose_____
7. Other symptoms_____
8. Pulling at Ears_____
9. Earache_____
10. Ear drainage_____
11. No Symptoms_____

Do you think the infection has cleared up? YES_____ NO_____

What antibiotic was the child on?_____

Did the child take all of the medication as ordered?_____

How many days did your child have symptoms after starting antibiotic treatment_____

Does the child have a history of recurrent ear infections? YES_____ NO_____

Is there a family history of recurrent ear infections? YES_____ NO_____

Has the child been seen by any health care provider since diagnosed with the ear infection?_____If yes, where and why_____

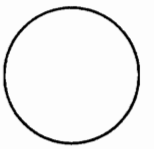
Thank you for your time !!

APPENDIX E

FOLLOW-UP VISIT PROVIDER EXAM

Left TM—Color: Grey Mobility: Mobile

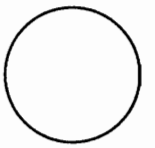
Pink Decreased mobility
Red Immobile
Yellow



Shiny_____ Dull_____ Bulging_____ Air/Fluid Level_____Perforation_____

Not Visualized_____ PET present_____

Right TM-- Color: Grey Mobility: Mobile
Pink Decreased mobility
Red Immobile
Yellow



Shiny_____ Dull_____ Bulging_____ Air/Fluid Level_____Perforation_____

Not Visualized_____ PET present_____

Normal Exam_____

BOM_____LOM_____ROM_____SOM_____OME_____

Concurrence with parental report YES_____ NO_____

APPENDIX F

EAR RECHECK FORM

Finished 10 d of _____, _____d ago. On d__of 10 of _____.

S: Asymptomatic Ear pain R L

Ear Tugging Fever

URI sx's

O: Temp:

TM-right- gray, pink, red Not Visualized

Shiny, dull, air/fluid level

Mobile, decreased mobility, immobile

TM-left- gray, pink, red Not Visualized

Shiny, dull, air/fluid level

Mobile, decreased mobility, immobile

PET: R PET: patent, draining, blocked, in canal

L PET: patent, draining, blocked, in canal

A: Resolved AOM SOM Bilat R L

P; Meds

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